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Practitioner's Docket No. CYNO - 4

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Box Patent Application Assistant Commissioner for Patents Washington, D.C. 20231

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of

Inventor(s): CHD, George E.

FURUMOTO, Horace

WARNING: Patent must be applied for in the name(s) of all of the actual inventor(s). 37 CFR 1.41(a) and 1.53(b)

For (title): SYSTEM AND METHOD FOR NOW- INVASIVE

WRINKLE REHOVAL AND SKIN TREATHENT

CERTIFICATION UNDER 37 C.F.R. 1.10* (Express Mail label number is mandatory.)

(Express Mail label number is mandatory. (Express Mail certification is optional.)

I hereby certify that this New Application Transmittal and the documents referred to as attached therein are being deposited with the United States Postal Service on this date 11 Jour (448 in an envelope as "Express Mail Post Office to Addressee," mailing Label Number EE 32 77 64447 U) addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

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(Application Transmittal [4-1]—page 1 of 9)

1. Type of Application	
This new application is for a(n)	
(check	one applicable item below)
🔀 Original (nonprovisional)	
Original (nonprovisional) Design	
☐ Plant	
	for a completion in the U.S. of an International Application under 35 International Application is being filed as a divisional, continuation or ion.
WARNING: Do not use this transmittal	
TRANSMITTAL WHERE BENEFI	ly, then complete and attach ADDED PAGES FOR NEW APPLICATION T OF A PRIOR U.S. APPLICATION CLAIMED and a NOTIFICATION HE FILING OF THIS CONTINUATION APPLICATION.
☐ Divisional.	
☐ Continuation.	
□ Continuation-in-part (C-	I-P).
2. Benefit of Prior U.S. Applicat	tion(s) (35 U.S.C. 119(e), 120, or 121)
case, or where the parent case of a prior provisional application	mitted is a divisional, continuation or a continuation-in-part of a parent is an International Application which designated the U.S., or benefit is claimed, then check the following item and complete and attach ICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICA-
120, 121 or 365(c), the 20-y earliest U.S. application that (35 U.S.C. 154(a)(2) does n application on which priori application, applicant should by an earlier application and	penefit of the filing date of an earlier filed application under 35 U.S.C. rear term of that application will be based upon the filing date of the the application makes reference to under 35 U.S.C. 120, 121 or 365(c), ot take into account, for the determination of the patent term, any ty is claimed under 35 U.S.C. 119, 365(a) or 365(b).) For a c-i-pd review whether any claim in the patent that will issue is supported if, if not, the applicant should consider canceling the reference to the erm of a patent is not based on a claim-by-claim approach. See Notice Reg. 20,195, at 20,205.
holiday within the District of	ncy of a provisional application falls on a Saturday, Sunday, or Federal of Columbia, any nonprovisional application claiming benefit of the the filed prior to the Saturday, Sunday, or Federal holiday within the 7 C.F.R. § 1.78(a)(3).
tion(s). Enclosed are AD	ng transmitted claims the benefit of prior U.S. applica- DED PAGES FOR NEW APPLICATION TRANSMITTAL RIOR U.S. APPLICATION(S) CLAIMED.
(Regular) or 37 C.F.R. 1.153 7 Pages of specification plants 3 Pages of claims plants 1 Pages of Abstract plants 2 Sheets of drawing 1 formal	
🔼 informal	

WARNING: DO NOT submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to § 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. Comments on proposed new 37 CFR 1.84. Notice of March 9, 1988 (1990 O.G. 57-62).

NOTE: "Identifying indicia, if provided, should include the application number or the title of the invention, inventor's name, docket number (if any), and the name and telephone number of a person to call if the Office is unable to match the drawings to the proper application. This information should be placed on the back of each sheet of drawing a minimum distance of 1.5 cm. (5/8 inch) down from the top of the page." 37 C.F.R. 1.84(c)).

	·	i tile page. 37 C.F.M. 1.04(c)).	
		(complete the following, if applicable)	
		The enclosed drawing(s) are photograph(s), and there is also attached a "PETITION TO ACCEPT PHOTOGRAPH(S) AS DRAWING(S)." 37 C.F.R. 1.84(b).	
4.	Addit	ional papers enclosed	
		Preliminary Amendment	
		Information Disclosure Statement (37 C.F.R. 1.98)	
		Form PTO-1449 (PTO/SB/08A and 08B)	
		Citations	
		Declaration of Biological Deposit	
		Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence.	
		Authorization of Attorney(s) to Accept and Follow Instructions from Representative	
	☐ Special Comments		
		Other	
5. Declaration or oath □ Enclosed		ration or oath	
		(check all applicable boxes)	
		inventor(s).	
		legal representative of inventor(s). 37 CFR 1.42 or 1.43.	
		joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.	
		☐ This is the petition required by 37 CFR 1.47 and the statement	

Not Enclosed.

Where the filing is a completion in the U.S. of an International Application, but where a declaration is not available, or where the completion of the U.S. application contains subject matter in addition to the International Application, the application may be treated as a continuation or continuation-in-part, as the case may be, utilizing ADDED PAGE FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION CLAIMED.

required by 37 CFR 1.47 is also attached. See item 13 below for

Application is made by a person authorized under 37 C.F.R. 1.41(c) on behalf of all the above named inventor(s).
(The declaration or oath, along with the surcharge required by 37 CFR 1.16(e) can be filed subsequently).
NOTE: It is important that all the correct inventor(s) are named for filing under 37 CFR 1.41(c) and 1.53(b).
Showing that the filing is authorized. (not required unless called into question, 37 CFR 1.41(d))
6. Inventorship Statement
WARNING: If the named inventors are each not the inventors of all the claims an explanation, including the ownership of the various claims at the time the last claimed invention was made, should be submitted.
The inventorship for all the claims in this application are:
☆ The same.
(or
Not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made,
is submitted.
☐ will be submitted.
7. Language
NOTE: An application including a signed oath or declaration may be filed in a language other than English. A verified English translation of the non-English language application and the processing fee of \$130.00 required by 37 CFR 1.17(k) is required to be filed with the application, or within such time as may be set by the Office. 37 CFR 1.52(d).
NOTE: A non-English oath or declaration in the form provided or approved by the PTO need not be translated. 37 CFR 1.69(b).
English
⁽ □ Non-English
☐ The attached translation is a verified translation. 37 C.F.R. 1.52(d).
8. Assignment
An assignment of the invention to CYNOSURE, INC
·
is attached. A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1595 is also attached.
will follow.
NOTE: "If an assignment is submitted with a new application, send two separate letters-one for the application and one for the assignment." Notice of May 4, 1990 (1114 O.G. 77-78).

WARNING: A newly executed "CERTIFICATE UNDER 37 CFR 3.73(b)" must be filed when a continuation--n-part application is filed by an assignee. Notice of April 30, 1993, 1150 O.G. 62-64.

9. Certified	Copy
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Certified copy(ies) of application(s)

Country	Appln. No.	_	Filed
Country	Appln. No.		Filed
Country	Appln. No.		Filed
from which priority is claimed			
is (are) attached.			
☐ will follow.			
NOTE: The foreign application for declaration. 37 CFR 1.55(a	ming the basis for the claim for and 1.63.	priority must be	referred to in the oath o
U.S. application or Internat 120 is itself entitled to prio	n priority for which the application ional Application from which this writy from a prior foreign application TRANSMITTAL WHERE	application claim	s benefit under 35 U S C e item 18 on the ADDED
10. Fee Calculation (37 C.F	F.R. 1.16)		
A. Regular application	1		
	CLAIMS AS FILED		· · · · · · · · · · · · · · · · · · ·
Number filed	Number Extra	Rate	Basic Fee 37 C.F.R. 1.16(a) \$790.00
Total			_
Claims (37 CFR 1.16(c)) 12-	20 = ×	\$ 22.00	
Independent Claims (37 CFR 1.16(b))	3 = ×	\$ 82.00	
Multiple dependent claim(s), if any (37 CFR 1.16(d))	+	\$270.00	
☐ Amendment cance	lling extra claims is enclo	sed.	
Amendment deleting	ng multiple-dependencies	is enclosed.	
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Filing Fee Calculation

В.		Design application (\$330.00—37 CFF		
			Filing Fee Calculation	\$
C.		Plant application (\$540.00—37 CFF		œ.
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☐ End	closed	
	Filing fee	\$
	Recording assignment (\$40.00; 37 C.F.R. 1.21(h)) (See attached "COVER SHEET FOR ASSIGNMENT ACCOMPANYING NEW APPLICATION".)	\$
	Petition fee for filing by other than all the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached (\$130.00; 37 C.F.R. 1.47 and 1.17(h))	\$
	For processing an application with a specification in a non-English language (\$130.00; 37 C.F.R. 1.52(d) and 1.17(k))	\$
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	Fee for international-type search report (\$40.00; 37 C.F.R. 1.21(e))	\$
to com 1.53 an filing fe	1.21(f) establishes a fee for processing and retaining any application polete the application pursuant to 37 CFR 1.53(d) and this, as well 1.78, indicate that in order to obtain the benefit of a prior U.S. a must be paid, or the processing and retention fee of § 1.21(f) mutton under § 53(d).	ell as the changes to 37 CFR application, either the basic
	Total fees enclosed	\$
14. Method	of Payment of Fees	
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NOTE: Fees sh 1.22(b).	ould be itemized in such a manner that it is clear for which purpo	se the fees are paid. 37 CFR

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15. Autho	orization to Charge Additional	Fees
WARNING:	If no fees are to be paid on filing, th	e following items should <u>not</u> be completed.
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		uthorized to charge the following additional fees tire pendency of this application to Account No.
1	☐ 37 C.F.R. 1.16(a), (f) or (g)	(filing fees)
l	☐ 37 C.F.R. 1.16(b), (¢) and ((d) (presentation of extra claims)
mu set aut	ist only be paid or these claims cancell for response by the PTO in any notice	ole dependent claims not paid on filing or on later presentation led by amendment prior to the expiration of the time period e of fee deficiency (37 CFR 1.16(d)), it might be best not to m fees, except possibly when dealing with amendments after
1	, , ,	e for filing the basic filing fee and/or declaration ing date of the application)
	☐ 37 C.F.R. 1.17 (application	processing fees)
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ent fee the	tity status must be filed in the applicati ." From the wording of 37 CFR 1.28(b	ny change in status resulting in loss of entitlement to small on prior to paying, or at the time of paying, issue), (a) notification of change of status must be made even in " and (b) no notification is required if the change is to another
16. Instru	ictions as to Overpayment	
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		Plus Added Pages for New Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed
		Number of pages added
		Plus Added Pages for Papers Referred to in Item 4 Above
		Number of pages added
		Plus "Assignment Cover Letter Accompanying New Application"
		Number of pages added
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System and Method for Non-invasive Wrinkle Removal and Skin Treatment

Background of the Invention

Field of The Invention

The present invention relates to the field of resurfacing skin, or wrinkle removal using laser radiation for treatment of underlying layers of skin.

Prior Art

Plastic surgeons, dermatologists and their patients continually search for new and approved methods for treating the effects of an aging skin. Historically, the treatment of facial wrinkles was primarily accomplished with the use of chemical peels or dermabrasion. The use of chemical peels has fallen out of favor, because it is difficult to accurately control and predict the depth of tissue injury after such peels are applied. Deeper chemical peels in particular have an increased risk of hypopigmentation and scarring. Such injury to the top layer of skin, which would be peeled away, would permit new cells to supposedly rejuvenate the skin. A less expensive way of injuring the outer layer of the skin is the utilization of an abrasive wheel, to rough off the skin layer. This method is not well controlled, and is very difficult especially around the eyelids.

Laser skin resurfacing began with a carbon dioxide laser. The carbon dioxide laser energy is absorbed by tissue water causing vaporization of the outer skin layer. Carbon dioxide lasers have been utilized for approximately 3 decades. However it has only been the past few years that these lasers have been arranged to remove only thin tissue layers with minimal heat damage to the surrounding skin. While carbon dioxide lasers may remove about 150 microns of skin, that skin may take a month or more to heal under such a procedure.

Er:YAG lasers have been utilized to ablate even thinner layers of tissue than carbon dioxide layers. However they lack the coagulation characteristics and thus allow more bleeding than a carbon dioxide laser during use:

Non-ablative skin resurfacing, is a methodology which does not take the top layer of skin off, but which shrinks the collagen under that skin, and modifies that collagen, so that the wrinkled skin appears to be fill-in by the collagen modified beneath the skin. This methodology however, has a low efficiency, and a cryogen coolant must be sprayed on to the skin so as to minimize damaging the top or upper layer thereof and also to minimize pain generation. The "fluence" or energy density used is greater than 10 joules per square centimeter and to be more effective this fluence often reaches 30 Joules per square centimeter. This level of energy often causes pain and epidermal damage.

It is an object of the present invention to improve upon the shortcomings of the prior art.

It is yet a further object of the present invention to provide a skin resurfacing laser treatment, which is nonablative, and minimizes any pain to the patient being treated.

It is yet still a further object of the present invention, to provide a new method to stimulate the collagen beneath the skin surface, to improve the surface appearance from beneath that surface of skin of the patient.

Brief Summary of The Invention

The present invention comprises a system and methodology for noninvasive wrinkle removal for the modification of collagen beneath the epidermis. The laser system of the present invention, in a preferred embodiment, utilizes a pulsed dye laser having a deep penetrating wavelength of about 585 nanometers (nm) laser, so as to target hemoglobin of blood in the skin tissue. This particular laser energy is absorbed by the hemoglobin. The heat is generated in the skin area up to about 1 mm in depth and typically uses energy of less than 5 Joules per square cm, having a preferred target spot size of about 10 mm diameter.

The pulsed dye laser apparatus of the present invention includes a handpiece connected by an optical fiber or wave guide, critically, to a pulsed dye laser generator device.

The handpiece focuses, through a plurality of lenses, the pulsed dye laser light from the pulsed dye laser generator, onto the spot of about 10 mm in diameter, so as to stimulate new collagen growth beneath the epidermis without injuring the surrounding structures.

In the preferred embodiment of the present invention, the pulse width has a range of 150 microseconds to about 1500 microseconds with a preferred width of about 450 microseconds. The wavelength of the pulsed dye laser apparatus of the present invention lies in a range of about 570 nanometers to about 650 nanometers, with a preferred wavelength of about 585 nanometers. The present invention provides a preferred fluence of less than 5 Joules per square cm., and preferably 3 Joules per square cm at a 10-millimeter diameter skin treatment spot.

By treating the skin to this low fluence pulsed dye laser light, collagen may be stimulated to regenerate and "fill in" valleys of wrinkles for a younger more clearer skin.

Thus what has been shown is a new method of stimulating modification of the collagen layer at a depth of at least about 1 mm to about 1.2 mm beneath the skin surface,

utilizing a low energy level of less than 5 Joules per square cm., in a manner not appreciated by the prior art.

The invention thus comprises a method for the treatment of wrinkles on human skin, by stimulating collagen growth beneath the epidermis layer, comprising the steps of: arranging a pulsed dye laser generator in light communication with a pulsed dye laser delivery device; applying said pulsed dye laser delivery device against tissue having wrinkles; generating a pulsed dye laser light by said pulsed dye laser; and directing said pulsed dye laser light from said pulsed dye laser delivery device onto said tissue, to reach hemoglobin in a collagen layer beneath the surface of said tissue. The method includes the step of: tuning said pulsed dye laser to deliver a laser light at a wavelength having a range of from about 570 nanometers to about 650 nanometers, and adjusting said range of pulsed dye laser light generated to a wavelength of about 585 nanometers. The pulsed dye laser has a pulse width in a range of from about 150 microseconds to about 1500 microseconds. Preferably the pulsed dye laser has a pulse width of about 450 microseconds. The method included the pulsed dye laser light being directed at the tissue at a target spot diameter of about 10 mm. The method includes maintaining a fluence of the pulsed dye laser light of less than 5 Joules per square cm.

Brief Description of the Drawings

The objects and advantages of the present invention will become more apparent, when viewed in conjunction with the following drawings, in which:

Figure 1 is a schematic representation of the laser apparatus of the present invention, as it is applied to a layer of skin; and

Figure 2 is a graph showing the absorption characteristics of certain body tissue chromophors versus laser wavelength.

Description of the Preferred Embodiments

Referring now to the drawings in detail, and particularly to figure 1, there is shown the present invention, which comprises a system 10, and methodology for noninvasive wrinkle removal for the modification of collagen beneath the epidermis. The laser system 10 of the present invention, in a preferred embodiment, utilizes a pulsed dye laser 12 having a deep tissue-penetrating wavelength of about 585 nanometers (nm) laser, so as to target hemoglobin "H" of blood in the skin tissue "T". The preferred pulsed dye laser 12 generates a particular laser wavelength energy of 585 nanometers, which is absorbed by the hemoglobin "H". The heat is generated in the skin tissue "T" area up to about 1 mm in depth and typically uses energy of less than 5 Joules per square cm, having a preferred target spot size "S" of about 10 mm diameter circle or larger.

The pulsed dye laser apparatus 12 of the present invention includes a handpiece 14 connected by an optical fiber or wave guide 16, critically, to a pulsed dye laser generator for generating the particular wavelength and fluence of the present invention.

The handpiece 14 focuses, through a plurality of lenses 20 and 22, the pulsed dye laser light "L" from the pulsed dye laser generator 12, onto the spot "S" of about 10 mm in diameter or larger, so as to stimulate new collagen growth beneath the epidermis "E".

In the preferred embodiment of the present invention, the pulse width has a range of 150 microseconds to about 1500 microseconds with a preferred width of about 450 microseconds. The wavelength of the pulsed dye laser apparatus 12 of the present invention lies in a range of about 570 nanometers to about 650 nanometers, with a preferred wavelength of about 585 nanometers. The present invention provides a preferred fluence of less than 5 Joules per square cm., and preferably 3 Joules per square cm at a 10-millimeter diameter skin treatment spot "S".

By treating the skin "T" to this low fluence pulsed dye laser light "L", the collagen beneath the epidermis, that is below about .06 mm. beneath the surface may be stimulated to regenerate and "fill in" valleys of wrinkles for a younger more clearer skin.

Thus what has been shown is a new method of stimulating modification of the collagen layer at a depth of up to about 1 mm to about 1.2 mm beneath the skin surface, utilizing a low energy level of less than 5 Joules per square cm., in a manner not appreciated by the prior art.

We Claim:

A method for the treatment of wrinkles on human skin, by stimulating collagen growth beneath the epidermis layer, comprising the steps of:

arranging a pulsed dye laser generator in light communication with a pulsed dye laser delivery device;

applying said pulsed dye laser delivery device against tissue having wrinkles; generating a pulsed dye laser light by said pulsed dye laser; and

directing said pulsed dye laser light from said pulsed dye laser delivery device onto said tissue, to reach hemoglobin in a collagen layer beneath the surface of said tissue.

- 2. The method of treatment of wrinkles as recited in claim 1, including the step of: tuning said pulsed dye laser to deliver a laser light at a wavelength having a range of from about 570 nanometers to about 650 nanometers.
- 3. The method of treatment of wrinkles as recited in claim 2, including the step of:
 adjusting said range of pulsed dye laser light generated to a wavelength of about
 585 nanometers.
- 4. The method of treatment of wrinkles as recited in claim 1, including the step of: generating said pulsed dye laser at a pulse width in a range of from about 150 microseconds to about 1500 microseconds.

- 5. The method of treatment of wrinkles as recited in claim 4, including the step of: generating said pulsed dye laser at a pulse width of about 450 microseconds.
- 6. The method of treatment of wrinkles as recited in claim 1, including the step of: directing said pulsed dye laser light at the tissue at a target spot diameter of about 10-mm.
- 7. The method of treatment of wrinkles as recited in claim 1 including the step of: maintaining a fluence of said pulsed dye laser light of less than 5 Joules per square cm.
- A method for the treatment of wrinkles on human skin, by stimulating collagen growth beneath the epidermis layer, comprising the steps of:

arranging a pulsed dye laser generator in light communication with a pulsed dye laser delivery device;

applying said pulsed dye laser delivery device against tissue having wrinkles;

generating a pulsed dye laser light by said pulsed dye laser; and directing said pulsed dye laser light from said pulsed dye laser delivery device onto said tissue, to reach hemoglobin in a collagen layer beneath the surface of said tissue; and

tuning said pulsed dye laser to deliver a laser light at a wavelength having a range of from about 570 nanometers to about 650 nanometers.

- 9. The method of treatment of wrinkles as recited in claim 8, including the step of:
 adjusting said range of pulsed dye laser light generated to a wavelength of
 about 585 nanometers.
- 10. The method of treatment of wrinkles as recited in claim 9, including the step of:

 generating said pulsed dye laser at a pulse width in a range of from about

 150 microseconds to about 1500 microseconds.
- 11. The method of treatment of wrinkles as recited in claim 10, including the step of:

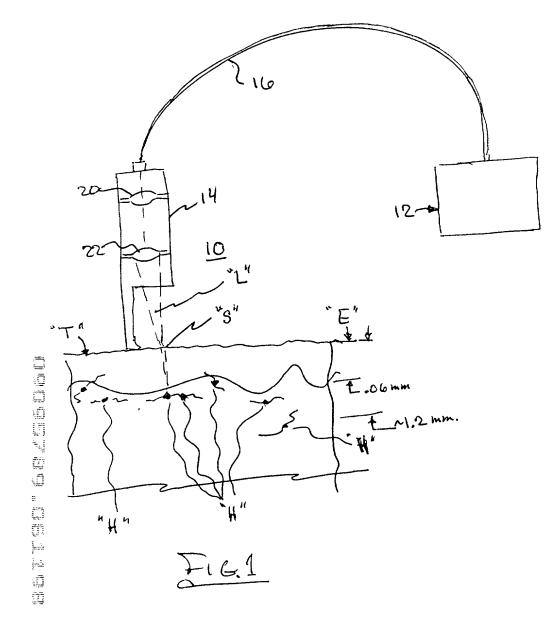
 generating said pulsed dye laser at a pulse width of about 450 microseconds.
- 12. The method of treatment of wrinkles as recited in claim 10, including the step of:

 energizing said collagen down to a depth of about 1.0-mm to about 1.2mm.

 below the surface of the skin by said pulsed dye laser.

Abstract of the Disclosure

The present invention includes a system and method for the treatment of wrinkles on human skin, by stimulating collagen growth beneath the epidermis layer, comprising the steps of: arranging a pulsed dye laser generator in light communication with a pulsed dye laser delivery device. The pulsed dye laser delivery device is applied against tissue having wrinkles. The pulsed dye laser generator generates a pulsed dye laser light. A pulsed dye laser light from the pulsed dye laser delivery device is directed onto the tissue, to reach hemoglobin in a collagen layer up to about 1.2mm. beneath the surface of the tissue to effect growth changes therein.



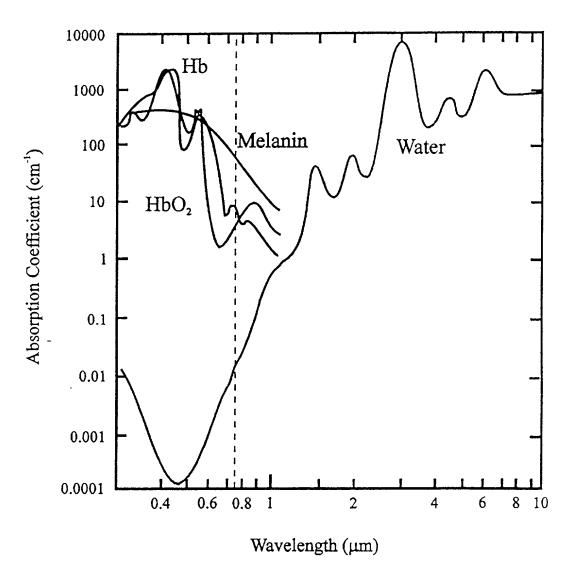
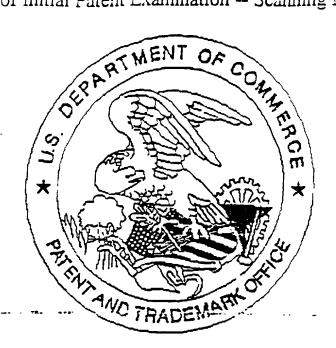


Fig 2

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Unica States Patent & Trademark Uffice

Office of Initial Patent Examination - Scanning Division



Application deficiencies found during scanning:

	oplication papers are not suitable for scanning and are not in compliance with 37 CFR cause:
	All sheets must be the same size and either A4 (21 cm x 29.7 cm) or 8-1/2"x 11"
	Pages do not meet these requirements.
	Papers are not flexible, strong, smooth, non-shiny, durable, and white.
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	2.5 cm (1") and top, bottom and right margins of at least 2.0 cm (3/4").
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